AMENDMENTS TO THE SPECIFICATION:

Amend the paragraphs appearing at page 12, lines 4-32, as follows:

Example 2

Dissolution of drospirenone from tablets

The rate of dissolution of drospirenone from the tablets prepared in Example 1 ~~was~~ is determined by the USP XXIII Paddle Method using a USP Dissolution Test Apparatus 2 including 6 covered glass vessels and 6 paddles. Tablets ~~were~~ are placed in 900 ml water at a temperature of 37°C (± 0.5°C) and stirred at 50 rpm.

The results appear from Figs. ~~1, 2 and 4~~ 1, 2 and 3. From Fig. 1, it appears that the batch numbered 718 containing macrocrystalline drospirenone (but otherwise identical to the tablets prepared in Example 1) ~~exhibited~~ exhibits an extremely slow dissolution rate of drospirenone, whereas all batches containing micronized drospirenone ~~exhibited~~ exhibit a dissolution rate of more than 70% within 30 minutes.

Fig. 2 and ~~Fig. 4 shows~~ Fig. 3 show the results of dissolution of drospirenone from tablet cores and film-coated tablets, respectively. In both cases more than 70% of the active agent is dissolved within 30 minutes. Thus, the film coating ~~did~~ does not significantly influence the rate of dissolution.

Example 3

Dissolution rate of ethinylestradiol from tablets in vitro

The rate of dissolution of ethinylestradiol from tablets prepared as described in Example 1 ~~was~~ is determined according to the USP Paddle Method as described in Example 2 for drospirenone. The results appear from ~~Figs. 3~~ Figs. 4 and 5 showing the dissolution rates from tablet cores and film-coated tablets, respectively. In both cases, more than 70% of the active agent ~~was~~ is dissolved within 30 minutes. Thus, the film coating ~~did~~ does not significantly influence the rate of dissolution.

Amend the paragraphs at page 13, lines 26-34, as follows:

Example 5

Contraceptive efficacy of formulations containing drospirenone and ethinylestradiol

An open-label, randomized trial with 52 female volunteers aged 20-35 years whose informed consent ~~had been~~ is obtained ~~included~~ includes 1 pre-treatment cycle, 3 treatment cycles with two different ~~tablet~~ tablets containing 2 mg and 3 mg drospirenone, respectively, but otherwise corresponding to the tablets prepared in Example 1, and a follow-up phase. A wash-out phase of 1 month ~~preceded~~ precedes the treatment.

At defined time points, selected central and peripheral parameters ~~were~~ are investigated. LH, FSH, 17β-estradiol, progesterone, cervical score, "spinnbarkeit", fern phenomenon. Ovarian function was ~~is~~ checked by ultrasound. In addition, SHBG, CBG, prolactine, total testosterone, androstenedione, DHEA-S and selected metabolic parameters (serum glucose, triglycerides, cholesterol, HDL, LDL) ~~were~~ are examined. Blood pressure, heart rate, body weight and cycle control ~~were~~ is documented.

The results of the study ~~showed~~ show that both LH and FSH ~~were~~ are clearly suppressed

with both trial preparations. Accordingly, the secretion of estradiol and progesterone ~~were~~ are greatly reduced over all three treatment cycles with the exception of 3 volunteers receiving the 2 mg drospirenone preparation. This result ~~was~~ is, in principle, confirmed by the accompanying ultrasound examinations. Follicular ripening ~~occurred~~ occurs in several cases with both trial preparations. Although three ovulations ~~were~~ are diagnosed with the preparation containing 2 mg drospirenone (one of which was described as "equivocal" and the other as a "tablet-taking error"), no differences ~~were~~ are demonstrable statistically ($p > 0.05$) between the two trial preparations as regards the hormones LH, FSH, estradiol and progesterone, and the parameter "ovulation during the treatment cycles". In keeping with the hormones, cervical function ~~was~~ is greatly limited and the "spinnbarkeit" and crystallisability of the cervical mucus ~~was~~ is greatly reduced with both trial preparations. Prolactin ~~increased~~ increases minimally and SHBG and CBG distinctly with both preparations. Triglycerides and HDL levels ~~increased~~ increases with both trial preparations, while LDL levels ~~decreased~~ decrease. Total cholesterol ~~was~~ is largely unchanged in both treatment groups. Oral glucose tolerance ~~remained~~ remains virtually unchanged or ~~was~~ is slightly decreased. Testosterone, androstenedione and DHEA-S ~~decreased~~ decrease minimally.

The subjective and objective tolerance ~~was~~ is good with both treatments. This ~~was~~ is also the case for cycle control with the exception of the first cycle with 2 mg drospirenone. Blood pressure, heart rate and body weight ~~remained~~ remain constant in the majority of cases or ~~showed~~ show a slight tendency to decrease.

After three months' treatment, it ~~was~~ is concluded:

The two trial preparations ~~were~~ are equally good as regards the subjective and objective tolerance.

No negative metabolic effects ~~were~~ are observed with either preparation. HDL ~~was~~ is influenced positively in the sense of an increase.

The results ~~confirmed~~ confirm the results of earlier studies that the 2 mg drospirenone preparation ~~was~~ is in the threshold region of ovulation inhibition, whereas the 3 mg drospirenone preparation ~~had~~ has a demonstrable ovulation-inhibiting effect in all cases examined.